UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

REBECCA LYNNE PATTERSON, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. CABALETTA BIO, INC., STEVEN A. NICHTBERGER, ANUP MARDA, DAVID J. CHANG, CATHERINE BOLLARD, BRIAN DANIELS, RICHARD HENRIQUES, and MARK SIMON, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Rebecca Lynne Patterson ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Cabaletta Bio, Inc. ("Cabaletta" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired: (a) Cabaletta common stock pursuant and/or traceable to the Offering Documents (defined below) issued in connection with the Company's initial public offering conducted on or about October 24, 2019 (the "IPO" or "Offering"); and/or (b) Cabaletta securities between October 24, 2019 and December 13, 2021, both dates inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

2. Cabaletta, a clinical-stage biotechnology company, focuses on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases. The Company's proprietary technology utilizes chimeric autoantibody receptor (CAAR) T cells that are designed to selectively bind and eliminate B cells, which produce disease-causing autoantibodies or pathogenic B cells. Cabaletta's lead product candidate is DSG3-CAART, which is in Phase I clinical trial for the treatment of mucosal pemphigus vulgaris (the "Phase 1 Clinical Trial"), an autoimmune blistering skin disease, and Hemophilia A with Factor VIII alloantibodies.

3. On September 30, 2019, Cabaletta filed a registration statement on Form S-1 with the SEC in connection with the IPO, which, after amendment, was declared effective by the SEC on October 24, 2019 (the "Registration Statement").

4. On or about October 24, 2019, pursuant to the Registration Statement, Cabaletta's common stock began trading on the Nasdaq Global Select Market ("NASDAQ") under the trading symbol "CABA".

5. On October 25, 2019, Cabaletta filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement (the "Prospectus" and, together with the Registration Statement, the "Offering Documents").

6. Pursuant to the Offering Documents, Cabaletta conducted the IPO, selling approximately 6.8 million shares of common stock priced at $11.00 per share, for approximate proceeds of $69.5 million to the Company after applicable underwriting discounts and commissions, and before expenses.

7. The Offering Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing their preparation. Additionally, throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, the Offering Documents and Defendants made false and/or misleading statements and/or failed to disclose that: (i) top-line data of the Phase 1 Clinical Trial indicated that DSG3-CAART had, among other things, worsened certain participants' disease activity scores and necessitated additional systemic medication to improve disease activity after DSG3-CAART infusion; (ii) accordingly, DSG3-CAART was not as effective as the Company had represented to investors; (iii) therefore, the Company had overstated DSG3-CAART's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

8. On December 14, 2021, Cabaletta issued a press release "report[ing] top-line data on biologic activity from the two lowest dose cohorts in the DesCAARTes™ Phase 1 clinical trial of DSG3-CAART for the treatment of patients with mucosal Pemphigus Vulgaris

(mPV)." Among other results, Cabaletta reported that two cohort participants had "disease activity scores that worsened . . . after DSG3-CAART infusion" and thus "reduced or discontinued selected systemic therapies prior to DSG3-CAART infusion, as required by the protocol", while another participant "subsequently received systemic medication to improve disease activity after DSG3-CAART infusion."

9. On this news, Cabaletta's stock price fell $9.15 per share, or 73.14%, to close at $3.36 per share on December 14, 2021.

10. As of the time this Complaint was filed, the price of Cabaletta common stock continues to trade below the $11.00 per share Offering price, damaging investors.

11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

12. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

14. Venue is proper in this Judicial District pursuant to Section 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Cabaletta is headquartered in this

Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

15. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

16. Plaintiff, as set forth in the attached Certification, purchased or otherwise acquired Cabaletta common stock pursuant and/or traceable to the Offering Documents issued in connection with the IPO, and/or Cabaletta securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

17. Defendant Cabaletta is a Delaware corporation with principal executive offices located at 2929 Arch Street, Suite 600, Philadelphia, Pennsylvania 19104. Cabaletta's common stock trades in an efficient market on the NASDAQ under the trading symbol "CABA".

18. Defendant Steven A. Nichtberger ("Nichtberger") has served as Cabaletta's Chief Executive Officer at all relevant times. Nichtberger signed or authorized the signing of the Registration Statement filed with the SEC.

19. Defendant Anup Marda ("Marda") has served as Cabaletta's Chief Financial Officer at all relevant times. Marda signed or authorized the signing of the Registration Statement filed with the SEC.

20. David J. Chang ("Chang") has served as Cabaletta's Chief Medical Officer at all relevant times.

21. Defendants Nichtberger, Marda, and Chang are sometimes referred to herein collectively as the "Exchange Act Individual Defendants."

22. The Exchange Act Individual Defendants possessed the power and authority to control the contents of Cabaletta's SEC filings, press releases, and other market communications. The Exchange Act Individual Defendants were provided with copies of Cabaletta's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Cabaletta, and their access to material information available to them but not to the public, the Exchange Act Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Exchange Act Individual Defendants are liable for the false statements and omissions pleaded herein.

23. Cabaletta and the Exchange Act Individual Defendants are sometimes referred to herein collectively as the "Exchange Act Defendants."

24. Defendant Catherine Bollard ("Bollard") was a director of Cabaletta at the time of the IPO. Bollard signed or authorized the signing of the Registration Statement filed with the SEC.

25. Defendant Brian Daniels ("Daniels") was a director of Cabaletta at the time of the IPO. Daniels signed or authorized the signing of the Registration Statement filed with the SEC.

26. Defendant Richard Henriques ("Henriques") was a director of Cabaletta at the time of the IPO. Henriques signed or authorized the signing of the Registration Statement filed with the SEC.

27. Defendant Mark Simon ("Simon") was a director of Cabaletta at the time of the IPO. Simon signed or authorized the signing of the Registration Statement filed with the SEC.

28. The Exchange Act Individual Defendants and Defendants Bollard, Daniels, Henriques, and Simon are sometimes referred to herein collectively as the "Securities Act Individual Defendants."

29. As directors, executive officers, and/or major shareholders of the Company, the Securities Act Individual Defendants participated in the solicitation and sale of Cabaletta common stock in the IPO for their own benefit and the benefit of the Company. The Securities Act Individual Defendants were key members of the IPO working group and executives of the Company who pitched investors to purchase the shares sold in the IPO.

30. Cabaletta and the Securities Act Individual Defendants are sometimes referred to herein collectively as the "Securities Act Defendants."

31. The Exchange Act Defendants and the Securities Act Defendants are sometimes collectively, in whole or in part, referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

32. Cabaletta, a clinical-stage biotechnology company, focuses on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases. The Company's proprietary technology utilizes chimeric autoantibody receptor (CAAR) T cells that are designed to selectively bind and eliminate B cells, which produce disease-causing autoantibodies or pathogenic B cells. Cabaletta's lead product candidate is DSG3-CAART, which is in Phase I clinical trial for the treatment of mucosal pemphigus vulgaris, an autoimmune blistering skin disease, and Hemophilia A with Factor VIII alloantibodies.

33. On September 30, 2019, Cabaletta filed a registration statement on Form S-1 with the SEC in connection with the IPO, which, after amendment, was declared effective by the SEC on October 24, 2019.

34. On or about October 24, 2019, pursuant to the Registration Statement, Cabaletta's common stock began trading on the NASDAQ under the trading symbol "CABA".

35. On October 25, 2019, Cabaletta filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement.

36. Pursuant to the Offering Documents, Cabaletta conducted the IPO, selling approximately 6.8 million shares of common stock priced at $11.00 per share, for approximate proceeds of $69.5 million to the Company after applicable underwriting discounts and commissions, and before expenses.

Materially False and Misleading Statements Issued in the Offering Documents

37. In providing an overview of the Company, the Offering Documents stated, in relevant part:

> We are a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for B cell-mediated autoimmune diseases. Our proprietary technology utilizes chimeric autoantibody receptor, or CAAR, T cells that are designed to selectively bind and eliminate B cells that produce disease-causing autoantibodies, or pathogenic B cells, while sparing normal B cells. Our lead CAAR T cell product candidate was designed based on chimeric antigen receptor, or CAR, T cell technology that has been successfully developed and is marketed for the treatment of B cell cancers. We believe our technology, in combination with our proprietary Cabaletta Approach for selective B cell Ablation platform, called our CABA platform, has applicability across over two dozen B cell-mediated autoimmune diseases that we have identified, reviewed and prioritized. During the past two years, using our CABA platform, we have discovered and developed four product candidates, including our lead product candidate, to potentially treat patients with mucosal pemphigus vulgaris, or mPV, and three additional product candidates that have demonstrated specific and selective target engagement in vitro. In order to accelerate product development for our lead program and to access a proven cell therapy manufacturing platform, we have entered into a collaboration with the University of Pennsylvania, or Penn. We

hold multiple agreements with Penn to develop CAAR T cell therapies for the treatment of these diseases. Our goal is to leverage our team's expertise in autoimmunity and engineered T cell therapy and our Penn collaboration to rapidly discover and develop our portfolio of CAAR T product candidates.

***

We are pioneering the development of a new class of engineered T cell therapies that express CAARs to selectively engage and eliminate pathogenic B cells. By harnessing the power of targeted cell therapy, we believe our CABA platform, as developed by our team, has the potential to be a one-time curative therapy that may be a safer and more effective therapy option than current treatments. These efforts have attracted the leading investors, including Adage Capital Partners, 5AM Ventures, Boxer Capital, LLC of Tavistock Group, Cormorant Asset Management, Deerfield Management and RedMile Group as well as Penn.

Pipeline

We are developing a portfolio of CAAR T cell product candidates for the treatment of B cell-mediated autoimmune diseases. Our lead product candidate, DSG3-CAART, targets B cells that express pathogenic autoantibodies against the DSG3 protein, which cause mPV. The publication of the first in vivo evaluation of activity and toxicity of the product candidate in an animal model was followed by additional preclinical studies to support our IND submission. Our IND was accepted in September 2019, and we plan to open the first clinical trial site for our DSG3-CAART product candidate in 2020. Our next PV-directed product candidate, DSG3/1-CAART, is being designed to target B cells that give rise to pathogenic autoantibodies against either the DSG3 or DSG1 protein, which cause mcPV, and could address a broader PV population.

***

Our Approach

We are developing engineered T cell therapy candidates that express CAARs, which serve as "decoys" for antibodies expressed on the surface of B cells. Our CAAR T platform is based on the foundation of established CAR T therapeutics, differing primarily in their use of the antigen rather than an antibody fragment to target pathogenic B cells. We believe these CAARs enable the T cells to specifically engage and eliminate pathogenic B cells while sparing normal B cells. By harnessing the power of cell therapy, our technology has the potential to overcome the ability of these B cells to evade elimination and thus lead to durable responses.

In contrast to currently available therapies for B cell-mediated autoimmune diseases, we believe our CAAR T cells can recognize the specific autoantibodies that are responsible for causing an underlying disease and kill the cells that express the autoantibodies on their surface while preserving the rest of the humoral immune system. As a result, we believe CAAR T cell therapy used in B cell-mediated autoimmune diseases has the potential for durable elimination of pathogenic B cells and an associated elimination of clinical recurrences with an improved adverse event, or tolerability, profile relative to the current standard of care. We believe our technology has broad applicability, and we are building a portfolio of product candidates for B cell-mediated autoimmune diseases.

Our CABA Platform

We have developed our CABA platform to inform product candidate development from indication selection through preclinical studies. Using our CABA platform, our team has identified our highest priority target indications following a rigorous analysis of B cell-mediated autoimmune diseases. A deep understanding of the antigenic epitopes targeted in these diseases is required to design and construct a successful CAAR, a competency that we believe we are uniquely positioned to utilize in product candidate development. Finally, we evaluate preclinical activity and toxicity of our optimized CAAR constructs through in vitro and in vivo studies. We leverage the experience and insight gained from the development of each product candidate to improve the efficiency of our CABA platform in evaluating additional potential product candidates.

38. Further, in describing the Company's strategy, the Prospectus stated, in relevant part:

Our goal is to build upon our first mover advantage and expertise in cell therapies for B cell-mediated autoimmune diseases to accelerate the discovery, development and commercialization of our CAAR T cell therapies, with a focus on reliable manufacturing. We believe achieving this goal could result in potentially curative therapies for patients with unmet medical needs who suffer from certain B cell-mediated autoimmune diseases. To achieve this goal, key elements of our strategy include:

- ***Achieving clinical proof-of-concept for our lead product candidate, DSG3-CAART in mPV, the first in a series of well-understood and validated B cell-mediated autoimmune diseases for which we are developing CAAR T cell product candidates***. We believe our biologic understanding coupled with the well-understood clinical signs, symptoms and natural course of the disease, identify mPV as a model disease to evaluate our CAAR T approach. In addition, we have designed and developed DSG3-CAART, our lead product candidate that has demonstrated robust target engagement and no off-target toxicities in

preclinical studies. We believe our planned Phase 1 clinical trial evaluating DSG3-CAART for the treatment of mPV represents an optimal first opportunity to establish initial clinical proof-of-concept of our CABA platform.

- ***Leveraging our CABA platform to identify optimal targets for the CAAR T approach and apply learnings from DSG3-CAART to advance additional product candidates***. Shortly after inception, we undertook a comprehensive review of all known B cell-mediated autoimmune diseases in order to evaluate and prioritize the opportunity for selective destruction of B cells in an effort to cure B cell-mediated autoimmune diseases. We intend to continue to apply our proprietary learnings from DSG3-CAART, including scientific and regulatory learnings, to most effectively advance these additional opportunities.

- ***Expanding upon our established IP position and first mover advantage in CAAR T therapy targeted towards B cell-mediated autoimmune diseases***. We believe there is a particularly high value to the first mover advantage including, but not limited to, experience in discovery, preclinical development, regulatory efforts, intellectual property and insights from clinical trials that can be translated across programs. We are focused on protecting our intellectual property as we continue pursuing the development of future product candidates. We believe the issued U.S. patent on our initial CAAR constructs is the first patent covering cells engineered to express the known pathogenic epitopes recognized by DSG3 and DSG1 autoantibodies, which we are continuing to supplement with additional patent filings.

- ***Leveraging our cellular therapy experience and knowledge in addition to knowledge gained through our Penn collaboration to rapidly build our own fully-integrated internal infrastructure***. We have differentiated expertise that we believe is uniquely suited for the continued buildout of our CABA platform specializing in B cell-mediated autoimmune diseases. In combination with a management team possessing significant experience in executing on manufacturing strategies for cell therapy products, our partnership with Penn allows us to utilize their existing infrastructure, which accelerated our ability to submit our first IND. In parallel, we continue to build out an experienced team to develop and continue implementing a path to our manufacturing independence.

39. The statements referenced in ¶¶ 37-38 were materially false and misleading because the Offering Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading

and were not prepared in accordance with the rules and regulations governing their preparation. Specifically, the Offering Documents made false and/or misleading statements and/or failed to disclose that: (i) top-line data of the Phase 1 Clinical Trial indicated that DSG3-CAART had, among other things, worsened certain participants' disease activity scores and necessitated additional systemic medication to improve disease activity after DSG3-CAART infusion; (ii) accordingly, DSG3-CAART was not as effective as the Company had represented to investors; (iii) therefore, the Company had overstated DSG3-CAART's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

Materially False and Misleading Statements Issued During the Class Period

40. The Class Period begins on October 24, 2019, when Cabaletta's common stock began publicly trading on the NASDAQ pursuant to the materially false and misleading statements or omissions contained in the Offering Documents.

41. On January 29, 2020, Cabaletta issued a press release entitled, "FDA Grants DSG3-CAART Orphan Drug Designation for the Treatment of Pemphigus Vulgaris." The press release stated, in relevant part:

> Cabaletta [. . .] today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for the Company's lead product candidate, DSG3-CAART, for the treatment of pemphigus vulgaris (PV). DSG3-CAART is designed to target the cause of mucosal PV (mPV), B cells that express pathogenic autoantibodies directed against the DSG3 protein, while preserving normal B cell immune function.
>
> "Mucosal pemphigus vulgaris is a rare and potentially fatal, chronic autoimmune disease characterized by the loss of adhesion between cells of mucous membranes, resulting in widespread damage, painful blisters of the mucosal membranes, and increased susceptibility to life-threatening systemic infections," said David Chang, M.D., Chief Medical Officer of Cabaletta. "For affected patients, despite current treatment options, there is an urgent unmet need for more effective and durable therapies that can provide reliable, complete, and persistent remission from the

> disease beyond general immune suppression and B cell depletion provided by current treatment options. Orphan Drug Designation is an important recognition for investigational therapies for rare diseases and provides us with potentially valuable benefits as we prepare to initiate the DesCAARTes trial to generate and then report acute safety data from the first cohort of patients by the end of 2020."

42. On March 30, 2020, Cabaletta issued a press release announcing the Company's Q4 and full year 2019 financial results and providing a business update. The press release stated, in relevant part:

> "2019 was a foundational year highlighted by the FDA clearance of the IND for our lead product candidate, DSG3-CAART, for patients with mucosal pemphigus vulgaris (mPV). We obtained intellectual property protection and engaged with key partners to enable the rapid startup of this program, while at the same time making meaningful progress on our broader pipeline of additional programs," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "With respect to the COVID-19 pandemic, our top priority is to ensure the safety of our employees, collaborators, and others involved in our research and development efforts. As a result, we now anticipate a delay in reporting the acute safety data from the first cohort in the Phase 1 DesCAARTesTM trial. Once we have visibility on the impact of the pandemic, possibly during the second quarter of this year, we expect to issue revised guidance on our timeline for reporting the acute safety data from this trial. The recent extension of our cash runway until at least the end of the third quarter of 2022, two quarters beyond previous guidance, provides additional flexibility for the business."
>
> **Recent Business Highlights and Anticipated Upcoming Milestones**
>
> **DSG3-CAART**: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as potential treatment for patients with mucosal pemphigus vulgaris (mPV).
>
> - In September 2019, the U.S. Food and Drug Administration (FDA) cleared Cabaletta's first Investigational New Drug application (IND) for DSG3-CAART to initiate a first-in-human clinical trial of DSG3-CAART in patients with mPV.
>
> - In January 2020, the FDA granted DSG3-CAART Orphan Drug Designation for the treatment of PV.
>
> - The Company plans to initiate an open-label Phase 1 clinical trial (DesCAARTesTM) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients.

43. That same day, Cabaletta filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019 10-K"). The 2019 10-K contained substantively similar descriptions of the Company's overview, strategy, and approach as discussed, *supra*, in ¶¶ 37-38.

44. Appended to the 2019 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Nichtberger and Marda, attesting that "[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and result of operations of the Company."

45. On May 6, 2020, Cabaletta issued a press release entitled, "Cabaletta Bio Receives FDA Fast Track Designation for DSG3-CAART for the Treatment of Mucosal Pemphigus Vulgaris." The press release stated, in relevant part:

> Cabaletta [. . .] today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for DSG3-CAART (Desmoglein 3 Chimeric AutoAntibody Receptor T cells), the Company's lead product candidate for treatment of mucosal pemphigus vulgaris (mPV), for improving healing of mucosal blisters in patients with mPV.
>
> "We believe that this Fast Track Designation, coming shortly after the Orphan Drug Designation for DSG3-CAART, further demonstrates that mPV is a devastating, rare disease for which patients have limited treatment options resulting in a large unmet need. The Fast Track Designation represents an important next step in our clinical development plans," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. "We appreciate the benefits provided by this designation, including the opportunity for increased access to the FDA and potential acceleration of our clinical development path and regulatory review process."

46. On May 12, 2020, Cabaletta issued a press release announcing the Company's Q1 2020 results and providing a business update. The press release stated, in relevant part:

> "Following the recent Fast Track Designation from the FDA for our lead product candidate, DSG3-CAART, for the treatment of patients with mucosal pemphigus vulgaris (mPV), our Phase 1 DesCAARTes™ trial is ready to launch as soon as COVID-19 related clinical trial activity restrictions are lifted. mPV is a rare, serious, and sometimes fatal disease for which patients have limited treatment

options. We are eager to explore the potential of our engineered T cell therapy to fulfill this unmet need," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "We continue to closely monitor the unprecedented challenges and impact of the COVID-19 pandemic while working to ensure that patients, our employees and collaborators remain safe. As evidenced by the recent Fast Track designation, despite working from home over the past two months, our dedicated team continues to make progress across our portfolio wherever possible as we strive to develop potential cures for patients with severe autoimmune diseases."

Pipeline Highlights and Anticipated Upcoming Milestones

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T cells as potential treatment for patients with mucosal pemphigus vulgaris (mPV).

- In May 2020, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to DSG3-CAART. This follows the January 2020 granting of Orphan Drug Designation from the FDA for the treatment of PV.

- The Company is prepared to initiate an open-label Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients in 2020.

47. On August 6, 2020, Cabaletta issued a press release announcing the Company's Q2 2020 results and providing a business update. The press release stated, in relevant part:

"The recent initiation of patient recruitment in the DesCAARTesTM Phase 1 trial is an important milestone for Cabaletta that reflects the commitment of our outstanding team and academic partners to patients suffering with mucosal pemphigus vulgaris. This trial, evaluating the safety and tolerability of DSG3-CAART, is the first trial exploring whether a highly specific targeted cellular therapy can provide a deep and durable, perhaps curative, treatment for patients with a B cell-mediated autoimmune disease. We look forward to reporting acute safety data from the initial cohort by the first half of 2021," said Steven Nichtberger, M.D., Chief Executive Officer and co-founder of Cabaletta.

Pipeline Highlights and Anticipated Upcoming Milestones

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor (CAAR) T cells as potential treatment for patients with mucosal pemphigus vulgaris (mPV).

- The Company's open-label Phase 1 clinical trial (DesCAARTesTM) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory

mPV patients is now open for recruitment with clinical acute safety data from the initial cohort expected by the first half of 2021.

- In May 2020, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to DSG3-CAART, which provides independent validation of mPV as a serious and unmet medical need in patients.

48. On August 25, 2020, Cabaletta issued a press release entitled, "Cabaletta Bio Announces Publication of Comprehensive Preclinical Study Results for DSG3-CAART in Pemphigus Vulgaris." The press release stated, in relevant part:

> "We believe these comprehensive preclinical data for DSG3-CAART, published in The Journal of Clinical Investigation, support our approach to develop a durable, potentially curative, treatment for patients with mucosal pemphigus vulgaris," said Steven Nichtberger, M.D., Chief Executive Officer and co-founder of Cabaletta. "CAAR T cells represent a precision therapy approach designed to eliminate the underlying cause of B cell-mediated autoimmune diseases. The data also inform development of the multiple additional CAAR T therapies for B cell-mediated diseases that are in our pipeline."

49. On November 10, 2020, Cabaletta issued a press release announcing the Company's Q3 2020 financial results and providing a business update. The press release stated, in relevant part:

> "With patient enrollment now underway for our lead program, DSG3-CAART, for patients with mucosal pemphigus vulgaris, we are on track to report acute safety data from the first cohort of patients in the first half of next year. During the quarter, we opened a second site for the trial and also published comprehensive preclinical proof of concept data in The Journal of Clinical Investigation further validating the mechanism of action of DSG3-CAART," said Steven Nichtberger, M.D., Chief Executive Officer and co-founder of Cabaletta.
>
> **Pipeline Highlights and Anticipated Upcoming Milestones**
>
> **DSG3-CAART**: Desmoglein 3 chimeric autoantibody receptor (CAAR) T cells as potential treatment for patients with mucosal pemphigus vulgaris (mPV).
>
> - The Company's open-label Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV patients is actively recruiting patients at the first two sites in the U.S.

> The Company expects to report acute safety data from the initial cohort in the study in the first half of 2021.
>
> - In August 2020, the Company announced that comprehensive preclinical data for DSG3-CAART were published in The Journal of Clinical Investigation. These data demonstrated that DSG3-CAART achieved autoantibody elimination and resolution of blisters in an active immune mouse model of pemphigus vulgaris and that circulating soluble autoantibodies have the potential to enhance DSG3-CAART efficacy and did not demonstrate off-target toxicity.

50. On December 8, 2020, Cabaletta issued a press release entitled, "DesCAARTes™ Trial of DSG3-CAART for Treatment of Mucosal-Dominant Pemphigus Vulgaris." The press release stated, in relevant part:

> Cabaletta [. . .] today announced that the first patient has been dosed in the DesCAARTes™ Phase 1 clinical trial of DSG3-CAART for the treatment of patients with mucosal-dominant pemphigus vulgaris (mPV).
>
> "This is an important milestone in the development of our lead product candidate, DSG3-CAART, for patients with mucosal pemphigus vulgaris and for patients with B cell mediated autoimmune diseases more generally. We believe this is the first time a highly targeted, antigen specific cell therapy has been dosed in a patient with autoimmune disease. The study is designed to provide insights into the clinical effect of our precision CAAR T cell therapy in patients suffering from mPV," said David J. Chang, M.D., Chief Medical Officer of Cabaletta Bio. "Currently available therapies for mPV patients, including steroids, typically induce broad immunosuppression, offer modest efficacy and/or are associated with frequent relapses. DSG3-CAART therapy, which is engineered to target and specifically eliminate the cells responsible for generating disease-causing autoantibodies while preserving the healthy immune system, provides mPV patients the potential of a deep and durable response, perhaps even a cure."

51. On March 16, 2021, Cabaletta issued a press release announcing the Company's Q4 and full year 2020 financial results and providing a business update. The press release stated, in relevant part:

> "At the end of 2020, we achieved an important milestone when we dosed the first patient without any dose limiting toxicities in our Phase 1 clinical trial for DSG3-CAART, our lead product candidate being developed for the treatment of patients with mucosal pemphigus vulgaris. This is the first time a highly targeted, antigen specific cell therapy has been dosed in a patient with an autoimmune disease. We

continue to expect to report acute safety data from the initial cohort in this study in the first half of 2021 followed by additional topline data on any completed dose cohorts throughout the second half of 2021," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta.

***

Autoimmune Disease-Focused Pipeline Highlights and Anticipated Upcoming Milestones

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as potential treatment for patients with mucosal pemphigus vulgaris (mPV).

- In December 2020, the Company announced that the first patient was dosed in an open-label, multi-center Phase 1 clinical trial (DesCAARTes™) to evaluate the safety and tolerability of DSG3-CAART in relapsed/refractory mPV adult patients. The trial is actively enrolling patients across multiple sites in the U.S and is expected to enroll a total of approximately 30 patients. The Company expects to report acute safety data from the initial cohort in the study in the first half of 2021 followed by additional topline data on any completed dose cohorts throughout the second half of 2021.

- In August 2020, the Company announced that comprehensive preclinical data for DSG3-CAART were published in The Journal of Clinical Investigation. These data demonstrated that DSG3-CAART achieved autoantibody elimination and resolution of blisters in an active immune mouse model of pemphigus vulgaris and that circulating soluble autoantibodies have the potential to enhance DSG3-CAART efficacy and did not demonstrate off-target toxicity.

- In May 2020, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for DSG3-CAART for the improving healing of mucosal blisters in patients with mPV.

52. That same day, Cabaletta filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K contained substantively similar descriptions of the Company's overview, strategy, and approach as discussed, *supra*, in ¶¶ 37-38.

53. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by Defendants Nichtberger and Marda, attesting that "[t]he information contained in the [2020 10-

K] fairly presents, in all material respects, the financial condition and result of operations of the Company."

54. On May 3, 2021, Cabaletta issued a press release entitled, "Cabaletta Bio Reports Acute Safety Data from the First Dose Cohort in DesCAARTes™ Trial." The press release stated, in relevant part:

> Cabaletta [. . .] today announced acute safety data from the first dose cohort of the ongoing DesCAARTes™ Phase 1 clinical trial of DSG3-CAART for the treatment of patients with mucosal-dominant pemphigus vulgaris (mPV).
>
> "We are encouraged by the acute safety profile of DSG3-CAART in this initial low dose cohort. In the first cohort of three patients dosed with DSG3-CAART, there were no clinically relevant adverse events, including cytokine release syndrome or neurotoxicity, during the 8-day acute safety window, which we expect is the period with highest probability of observing treatment-related toxicities. In addition, no dose-limiting toxicities or clinically relevant adverse events were observed in the two patients who have completed more than the full 28-day DLT monitoring period post-infusion," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. These safety data were observed with an administered dose of 20 million DSG3-CAART cells, without preconditioning and in the presence of circulating anti-DSG3 antibodies; DSG3-CAART was detected at low levels via quantitative polymerase chain reaction in both patients who have been evaluated and completed the 28-day DLT period. The third patient is scheduled to be evaluated for presence of DSG3-CAART after the 28-day follow-up period.
>
> "The pace of the clinical trial is accelerating with the ongoing enrollment of patients and engagement of additional clinical sites. We believe these initial safety data represent an important step towards achieving our goal to offer a therapy that may provide deep and durable responses, and potentially cures, for patients in the pemphigus community," said Dr. Chang.

55. That same day, Cabaletta issued a press release announcing the Company's Q1 2021 financial results and providing new pipeline updates. The press release stated, in relevant part:

> "The initial safety data from the first low dose cohort of three patients in the DesCAARTes™ clinical trial for DSG3-CAART, our lead clinical candidate, support the acute safety profile of DSG3-CAART at the administered dose in mucosal-dominant pemphigus vulgaris patients, and are an encouraging indicator for the safety of the CAAR T platform overall. We look forward to reporting

additional topline data on safety and potential target engagement on completed dose cohorts throughout the second half of 2021," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta.

***

Acute Safety Data from First Dose Cohort of DesCAARTes™ Trial

Today, the Company reported results from the first cohort of three patients dosed with DSG3-CAART. There were no clinically relevant adverse events, including cytokine release syndrome or neurotoxicity, during the 8-day acute safety window, which the Company expects is the period with highest probability of observing treatment-related toxicities. In addition, no dose-limiting toxicities (DLTs) were observed in the first two subjects who have completed the 28-day DLT monitoring period post-infusion. The third patient has completed the 8-day acute safety window, and is in the DLT follow-up period. These safety data were observed with an administered dose of 20 million DSG3-CAART cells, without preconditioning and in the presence of circulating anti-DSG3 antibodies; DSG3-CAART was detected at low levels via quantitative polymerase chain reaction in both patients who have completed the 28-day DLT period and been evaluated. The third patient is scheduled to be evaluated for presence of DSG3-CAART after completion of the 28-day DLT monitoring period.

The DesCAARTes™ trial is currently enrolling patients in the second cohort at a treatment dose of 100 million DSG3-CAART cells. Infusions are planned to initiate following the third patient in the first cohort completing the 28-day monitoring period without any DLTs. Cabaletta expects to announce acute safety data for the second and third cohorts in the third and fourth quarters of 2021, respectively. Topline data on target engagement from the first cohort are anticipated during the second half of 2021. Cabaletta will continue to provide additional topline safety and target engagement data from the DesCAARTes™ trial once available on a cohort-by-cohort basis.

56. On August 5, 2021, Cabaletta issued a press release announcing the Company's Q2 2021 financial results and providing a business update. The press release stated, in relevant part:

"During the quarter, we did not observe any clinically relevant adverse events in the first, low-dose patient cohort of the DesCAARTes™ clinical trial for DSG3-CAART, our lead clinical product candidate for the treatment of patients with mucosal-dominant pemphigus vulgaris. We remain well-positioned to achieve multiple near-term clinical milestones for this program, including our plan to report safety data from the higher dose second and third patient cohorts in the third and fourth quarters of 2021, respectively, as well as target engagement data 3 to 6 months after each cohort is completed," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta.

***

Autoimmune Disease-Focused Pipeline Highlights and Anticipated Upcoming Milestones

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal-dominant pemphigus vulgaris (mPV).

- In May 2021, Cabaletta announced acute safety data from three patients in the first cohort in the DesCAARTes™ trial. As of August 4, 2021, no dose limiting toxicities (DLTs) or clinically relevant adverse events, including cytokine release syndrome or neurotoxicity, were observed. These safety data were observed with an administered dose of 20 million DSG3-CAART cells, without preconditioning and in the presence of circulating anti-DSG3 antibodies. DSG3-CAART was detected at low levels via qPCR in all three patients during the 28-day DLT monitoring window.

- In August 2021, with FDA clearance, a protocol amendment was implemented in the DesCAARTes™ trial to allow a minimum dosing interval of 7 days between patients within a cohort, versus 14 days.

- Cabaletta remains on track to announce 28-day safety data for the second and third cohorts in the third and fourth quarters of 2021, respectively, in addition to target engagement data 3 to 6 months after dosing of each cohort is completed. Cabaletta will continue to provide additional safety and top-line target engagement data from the DesCAARTes™ trial, once available, on a cohort-by-cohort basis.

57. On August 18, 2021, Cabaletta issued a press release entitled, "Cabaletta Bio Reports Clinical Data from the Second Dose Cohort in DesCAARTes™ Trial in Patients with mPV." The press release stated, in relevant part:

> Cabaletta [. . .] today announced 28-day data from the second dose cohort, at the 100 million cell dose level, in the DesCAARTes™ Phase 1 clinical trial of DSG3-CAART for the treatment of patients with mucosal-dominant pemphigus vulgaris (mPV).
>
> "We continue to be encouraged by the safety profile of DSG3-CAART in all patients dosed to date. In the second cohort, with patients receiving 100 million DSG3-CAART cells – a five-fold higher dose than the initial cohort – there were no clinically relevant adverse events or DLTs observed either acutely or in the 28-day DLT monitoring period following infusion," said David J. Chang, M.D., Chief

> Medical Officer of Cabaletta. "Similar to the first cohort, this safety profile was observed in the presence of circulating anti-DSG3 antibodies. In the absence of preconditioning, DSG3-CAART persistence was observed via quantitative polymerase chain reaction in peripheral blood samples of all three patients in the second dose cohort during the 28 days following infusion."
>
> In addition to assessing the safety and tolerability of DSG3-CAART, the trial is designed to evaluate early signs of efficacy through clinical outcomes, such as persistent decline in disease activity, reduction or discontinuation of immunosuppressive therapies and systemic corticosteroids, and absence of systemic rescue medication, as well as other biologic activity measures, including a persistent decline in anti-DSG3 antibody titers, indicating target engagement. "The persistence of DSG3-CAART post-infusion is also being evaluated as it may be an important indicator. We look forward to generating data on potential biologic activity, with the goal of providing a targeted and highly effective, and perhaps curative, therapy without generalized immunosuppression," continued Dr. Chang.

58. On November 1, 2021, Cabaletta issued a press release entitled, "Cabaletta Bio Reports Clinical Data from the Third Dose Cohort in DesCAARTes™ Trial in Patients with mPV."

The press release stated, in relevant part:

> Cabaletta [. . .] today announced 28-day clinical data from the third dose cohort using 500 million DSG3-CAART cells in the DesCAARTes™ Phase 1 clinical trial for the treatment of patients with mucosal-dominant pemphigus vulgaris (mPV).
>
> As of October 31, 2021, three patient cohorts in the DesCAARTes™ Phase 1 trial have completed DSG3-CAART dosing. The Company observed a dose dependent increase in DSG3-CAART persistence in the third cohort relative to the first two low dose cohorts throughout the 28 days following infusion. In addition, no clinically relevant adverse events or DLTs were observed during the 28-day monitoring period post-infusion. These safety data were observed without preconditioning, and in the presence of circulating anti-DSG3 antibodies.
>
> "We are highly encouraged by the observation of dose dependent increases in persistence as well as the continued absence of any DLTs or clinically relevant adverse events for DSG3-CAART across the first three cohorts, particularly in the presence of circulating anti-DSG3 antibodies and without lymphodepletion," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. "The rapid pace of the clinical trial has been possible due to the enthusiasm and engagement of patients, investigators and patient advocacy groups. With a 100% manufacturing success rate to date, we look forward to continuing to advance the trial until we identify a maximum tolerated dose and dosing regimen that has the potential to achieve a durable response while maintaining a favorable tolerability profile for patients suffering with mPV."

59. That same day, Cabaletta issued a press release announcing the Company's Q3 2021 financial results and providing a business update. The press release stated, in relevant part:

> "The DesCAARTes™ trial for DSG3-CAART for patients with mucosal-dominant pemphigus vulgaris has demonstrated encouraging momentum, with continued strong patient enrollment as well as new site and investigator engagement. Dose dependent increases in DSG3-CAART persistence in the third cohort through 28 days following infusion have been observed, as well as the continued absence of any DLTs or clinically relevant adverse events for the first three cohorts as of October 31, 2021. Our next anticipated data readout will include top-line biologic activity data from the first two low dose cohorts, which we expect to announce in the fourth quarter of 2021. We look forward to continuing to generate data on potential biologic activity as we proceed to higher dosing cohorts, with the goal of providing a targeted, highly effective, and potentially curative, therapy without generalized immunosuppression," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta.
>
> ***
>
> **Autoimmune Disease-Focused Pipeline Highlights and Anticipated Upcoming Milestones**
>
> **DSG3-CAART**: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal pemphigus vulgaris (mPV).
>
> - Observance of dose dependent DSG3-CAART persistence and favorable safety profile through cohort three of the DesCAARTes™ Phase 1 trial: The Company announced today that three patient cohorts in the DesCAARTes™ Phase 1 trial have completed DSG3-CAART dosing as of October 31, 2021. The Company observed a dose dependent increase in persistence of DSG3-CAART in the third 500 million cell cohort relative to the first two low dose cohorts throughout the 28 days following infusion. In addition, no clinically relevant adverse events or DLTs were observed during the 28-day monitoring period post-infusion. These safety data were observed without preconditioning, and in the presence of circulating anti-DSG3 antibodies. This safety profile builds off 28-day safety data from three patients in the second cohort that the Company reported in August 2021.
>
> - New site activations driving patient enrollment: As of October 31, 2021, three additional clinical sites were opened for recruitment, doubling the total number of activated DesCAARTes™ trial sites to six.

- Trial advancing through fourth patient cohort: Dosing was initiated in the fourth patient cohort at a dose of 2.5 billion DSG3-CAART cells. The Company anticipates announcing 28-day safety data for the fourth dose cohort in the first quarter of 2022.

- Near-term biologic activity data expected for the first two low dose cohorts: Cabaletta plans to announce top-line biologic activity data from the first two low dose cohorts in the fourth quarter of 2021.

60. The statements referenced in ¶¶ 40-59 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, the Exchange Act Defendants made false and/or misleading statements and/or failed to disclose that: (i) top-line data of the Phase 1 Clinical Trial indicated that DSG3-CAART had, among other things, worsened certain participants' disease activity scores and necessitated additional systemic medication to improve disease activity after DSG3-CAART infusion; (ii) accordingly, DSG3-CAART was not as effective as the Company had represented to investors; (iii) therefore, the Company had overstated DSG3-CAART's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

61. On December 14, 2021, Cabaletta issued a press release entitled, "Cabaletta Bio Reports Top-line Biologic Activity Data from Two Lowest Dose Cohorts in DesCAARTes™ Trial in Patients with Mucosal Pemphigus Vulgaris." Specifically, the press release stated, in relevant part:

> Cabaletta [. . .] today reported top-line data on biologic activity from the two lowest dose cohorts in the DesCAARTes™ Phase 1 clinical trial of DSG3-CAART for the treatment of patients with mucosal Pemphigus Vulgaris (mPV).
>
> As of December 12, 2021, six patients, comprising the two lowest dose cohorts (20 million and 100 million DSG3-CAART cells administered without lymphodepletion) had completed three to six months of follow-up for evaluation of

DSG3-CAART biologic activity. Patients enrolled had persistent mild to moderate disease severity prior to infusion despite receiving or having received systemic medication for treatment of their mPV symptoms prior to enrollment. Parameters being used in the trial to evaluate potential biologic activity include persistence of DSG3-CAART, change in level of DSG3 autoantibodies, change in mPV therapy or need for new systemic rescue therapy, and change in disease activity (e.g., as assessed by Pemphigus Disease Area Index (PDAI) and Oral Disease Severity Score (ODSS)). Prior to infusion, disease activity scores improved in five of six participants in the absence of any protocol directed additions to baseline therapy. Of those five participants, one had a decline in DSG3 autoantibody levels ≥20% during that period. Top-line data on biologic activity among the first six participants in the lowest dose cohorts are:

- *In cohort A1, participants received 20 million DSG3-CAART cells:*
    - *Two of three participants had DSG3 autoantibody levels that rose ≥20% along with disease activity scores (e.g., PDAI and ODSS) that worsened within six months after DSG3-CAART infusion, with one of these participants receiving additional systemic medication. Both participants reduced or discontinued selected systemic therapies prior to DSG3-CAART infusion, as required by the protocol.*
    - *One of three participants had modest DSG3 autoantibody levels and mild disease activity at infusion and had a negative DSG3 level at six months along with disease activity scores of zero on both scales at six months with no systemic medications for mPV since DSG3-CAART infusion. As permitted by protocol, this participant was enrolled due to worsening symptoms despite receiving two different systemic therapies within 9 months of DSG3-CAART infusion. The systemic therapies may have impacted clinical scores and DSG3 levels, both of which improved between screening and infusion.*
- *In cohort A2, participants received 100 million DSG3-CAART cells:*
    - *Two of three participants maintained stable DSG3 autoantibody levels that have not persistently changed +/- 20% of pre-infusion levels through four months. Through the six month follow-up period, one of these patients maintained stable disease activity scores, while the other patient maintained stable scores initially before subsequently worsening. Both patients did not require any new systemic medications post-infusion through the entire follow-up period.*
    - *One of three participants had DSG3 autoantibody levels that rose ≥20% from pre-infusion levels despite stable disease activity scores with four months of follow-up. This participant subsequently*

received systemic medication to improve disease activity after DSG3-CAART infusion.

- *DSG3-CAART persistence was not observed above the assay's threshold for quantification in any participant from the first two cohorts at three months post-infusion.*

Additional data on the initial cohorts in the DesCAARTes™ trial are anticipated to be presented at medical meetings and/or scientific sessions in 2022.

"As the first targeted cell therapy clinical trial for patients with a B cell-mediated autoimmune disease, the DesCAARTes™ trial was designed with patient safety as the top priority. By starting with these low-dose cohorts, we have been able to administer the product to autoimmune patients, with no dose-limiting toxicities or clinically relevant adverse events observed to date," reported David J. Chang, M.D., Chief Medical Officer of Cabaletta. "While clear signs of DSG3-CAART biologic activity were not observed to date in the two lowest cell dose cohorts, the emerging clinical and serological data in one of the six patients who has improved since DSG3-CAART infusion is notable. Patients in the fourth dosing cohort are currently being dosed with 2.5 billion cells, which is 25 and 125 fold greater than the two dose cohorts reported today. Based on communications with the U.S. Food and Drug Administration (FDA) dating to the first half of 2021, as well as the safety data reported from our first three dosing cohorts, we plan to expand the DesCAARTes™ trial to evaluate higher dose cohorts and consolidated dosing regimens and, subject to an IND amendment, an enhanced manufacturing process. Our engagements and interactions with patients, investigators, and advocacy groups have given us confidence that patients with mPV are highly interested in a deep, durable, and potentially curative therapy, and we look forward to advancing the trial to potentially identify an optimal dose regimen that maximizes the opportunity for patients to achieve those goals, while maintaining a favorable safety profile."

The first additional cohort in the dose escalation phase of the DesCAARTes™ trial is anticipated to be the A5 cohort, in which patients will receive between 5.0-7.5 billion DSG3-CAART cells with a consolidated fractionated infusion regimen including only two fractions – 30% followed by 70%. The planned enhanced manufacturing process aims to amplify the already present cell subtypes in the product in order to potentially improve product potency and trafficking to tissue where the target B cells reside.

"Based on the reported safety data from the first three cohorts, the observation of dose-dependent increases in persistence previously reported in Cohort A3 relative to the first two cohorts, and consultation with investigators, advisors, and the FDA, we now have the opportunity to expand the trial to evaluate higher dose cohorts, consolidated dosing and, subject to an IND amendment, an enhanced manufacturing process," said Steven Nichtberger, M.D., Chief

> Executive Officer and Co-founder of Cabaletta. "With six sites activated and dosing underway in the fourth cohort at a dose of 2.5 billion DSG3-CAART cells, we anticipate reporting top-line biologic activity from the 500 million cell cohort A3 as well as 28-day safety data from the 2.5 billion cell cohort in the first quarter of 2022."

62. On this news, Cabaletta's stock price fell $9.15 per share, or 73.14%, to close at $3.36 per share on December 14, 2021.

63. As of the time this Complaint was filed, the price of Cabaletta common stock continues to trade below the $11.00 per share Offering price, damaging investors.

64. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

65. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Cabaletta common stock pursuant and/or traceable to the Offering Documents issued in connection with the IPO, and/or Cabaletta securities during the Class Period; and were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

66. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Cabaletta securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or

thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Cabaletta or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

67. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

68. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

69. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public in the Offering Documents for the IPO, or during the Class Period, misrepresented material facts about the business, operations and management of Cabaletta;
- whether the Securities Act Individual Defendants negligently prepared the Offering Documents for the IPO and, as a result, the Offering Documents contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading, and were not prepared in accordance with the rules and regulations governing their preparation;
- whether the Exchange Act Individual Defendants caused Cabaletta to issue false and misleading financial statements during the Class Period;
- whether certain Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Cabaletta securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

70. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

71. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Cabaletta securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Cabaletta securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

72. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

73. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v.*

United States, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against the Exchange Act Defendants)

74. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

75. This Count is asserted against the Exchange Act Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

76. During the Class Period, the Exchange Act Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Cabaletta securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Cabaletta securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the Exchange Act Defendants, and each of them, took the actions set forth herein.

77. Pursuant to the above plan, scheme, conspiracy, and course of conduct, each of the Exchange Act Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Cabaletta securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Cabaletta's finances and business prospects.

78. By virtue of their positions at Cabaletta, the Exchange Act Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Exchange Act Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Exchange Act Defendants. Said acts and omissions of the Exchange Act Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Exchange Act Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

79. Information showing that the Exchange Act Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Exchange Act Defendants' knowledge and control. As the senior managers and/or directors of Cabaletta, the Exchange Act Individual Defendants had knowledge of the details of Cabaletta's internal affairs.

80. The Exchange Act Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Exchange

Act Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Cabaletta. As officers and/or directors of a publicly-held company, the Exchange Act Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Cabaletta's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Cabaletta securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Cabaletta's business and financial condition which were concealed by the Exchange Act Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Cabaletta securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by the Exchange Act Defendants, and were damaged thereby.

81. During the Class Period, Cabaletta securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Exchange Act Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Cabaletta securities at prices artificially inflated by the Exchange Act Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Cabaletta securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Cabaletta securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

82. By reason of the conduct alleged herein, the Exchange Act Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

83. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Exchange Act Individual Defendants)

84. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

85. During the Class Period, the Exchange Act Individual Defendants participated in the operation and management of Cabaletta, and conducted and participated, directly and indirectly, in the conduct of Cabaletta's business affairs. Because of their senior positions, they knew the adverse non-public information about Cabaletta's misstatement of income and expenses and false financial statements.

86. As officers and/or directors of a publicly owned company, the Exchange Act Individual Defendants had a duty to disseminate accurate and truthful information with respect to Cabaletta's financial condition and results of operations, and to correct promptly any public statements issued by Cabaletta which had become materially false or misleading.

87. Because of their positions of control and authority as senior officers, the Exchange Act Individual Defendants were able to, and did, control the contents of the various reports, press

releases and public filings which Cabaletta disseminated in the marketplace during the Class Period concerning Cabaletta's results of operations. Throughout the Class Period, the Exchange Act Individual Defendants exercised their power and authority to cause Cabaletta to engage in the wrongful acts complained of herein. The Exchange Act Individual Defendants, therefore, were "controlling persons" of Cabaletta within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Cabaletta securities.

88. Each of the Exchange Act Individual Defendants, therefore, acted as a controlling person of Cabaletta. By reason of their senior management positions and/or being directors of Cabaletta, each of the Exchange Act Individual Defendants had the power to direct the actions of, and exercised the same to cause, Cabaletta to engage in the unlawful acts and conduct complained of herein. Each of the Exchange Act Individual Defendants exercised control over the general operations of Cabaletta and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

89. By reason of the above conduct, the Exchange Act Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Cabaletta.

COUNT III

(Violations of Section 11 of the Securities Act Against the Securities Act Defendants)

90. Plaintiff repeats and incorporates each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness, or intentional misconduct.

91. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of the Class, against Defendants.

92. The Offering Documents for the IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

93. Cabaletta is the registrant for the IPO. Defendants named herein were responsible for the contents and dissemination of the Offering Documents.

94. As issuer of the shares, Cabaletta is strictly liable to Plaintiff and the Class for the misstatements and omissions in the Offering Documents.

95. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Documents were true and without omissions of any material facts and were not misleading.

96. By reasons of the conduct herein alleged, each Defendant violated, and/or controlled a person who violated Section 11 of the Securities Act.

97. Plaintiff acquired Cabaletta shares pursuant and/or traceable to the Offering Documents for the IPO.

98. Plaintiff and the Class have sustained damages. The value of Cabaletta common stock has declined substantially subsequent to and because of Defendants' violations.

COUNT IV

(Violations of Section 15 of the Securities Act Against the Securities Act Individual Defendants)

99. Plaintiff repeats and incorporates each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness, or intentional misconduct.

100. This Count is asserted against the Securities Act Individual Defendants and is based upon Section 15 of the Securities Act, 15 U.S.C. § 77o.

101. The Securities Act Individual Defendants, by virtue of their offices, directorship, and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Cabaletta within the meaning of Section 15 of the Securities Act. The Securities Act Individual Defendants had the power and influence and exercised the same to cause Cabaletta to engage in the acts described herein.

102. The Securities Act Individual Defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiff and the Class.

103. By virtue of the conduct alleged herein, the Securities Act Individual Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 28, 2022

Respectfully submitted,

THE ROSEN LAW FIRM, P.A

/s/ Jacob A. Goldberg
Jacob A. Goldberg
Gonen Haklay
101 Greenwood Avenue, Suite 440
Jenkintown, PA 19046
Telephone: (215) 600-2817
Facsimile: (212) 202-3827
Email: jgoldberg@rosenlegal.com
Email: ghaklay@rosenlegal.com

Liaison Counsel for Plaintiff

POMERANTZ LLP
Jeremy A. Lieberman
(*pro hac vice* application forthcoming)
J. Alexander Hood II
(*pro hac vice* application forthcoming)
Thomas H. Przybylowski
(*pro hac vice* application forthcoming)
600 Third Avenue
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
jalieberman@pomlaw.com
ahood@pomlaw.com
tprzybylowski@pomlaw.com

Counsel for Plaintiff